Non- or Minimally-Invasive Methods to Measure Biochemical Substances during Neonatal and Perinatal Patient Care and Research (R41)

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The official link for this solicitation is: http://grants.nih.gov/grants/guide/rfa-files/RFA-HD-16-028.html

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Available Funding Topics

- 001: Non- or Minimally-Invasive Methods to Measure Biochemical Substances during Neonatal and Perinatal Patient Care and Research (R41) ×

Non- or Minimally-Invasive Methods to Measure Biochemical Substances during Neonatal and Perinatal Patient Care and Research (R41)

Purpose

The primary purpose of this initiative is to stimulate translational research by inviting small businesses with bioengineering and biomedical expertise to collaborate to develop advanced, non- or minimally invasive methods for rapid measurement and monitoring of biochemical substances during the care of perinatal (pregnant women and newborn infants) and pediatric patient

populations. The methods should provide reliable measurements of commonly assessed biochemical substances helping maternal and neonatal patient care, including neonatal intensive care. The primary aim of this line of research is to develop approaches to reduce or eliminate pain and discomfort associated with obtaining blood or other products for clinical care and research in perinatal, neonatal, and pediatric patient populations.

The second objective of the FOA is to invite the bioengineering and biomedical scientists to develop lab-on-a-chip methods to measure biomarkers that could be applied for diagnostic and prognostic purposes during perinatal patient care and in clinical and translational research studies. The patient populations in which these can be used are pregnant and lactating women, newborn infants, and children of all ages.

Background

Despite major advances, neonatal and pediatric intensive care still involves performing painful needle punctures to obtain blood samples for routine clinical monitoring and to measure and monitor serum electrolytes and other biochemical substances to assess the status of metabolic, kidney, hepatic, and cardio-respiratory systems. Many studies have shown that repeated and prolonged painful experiences in infants and children can have deleterious effects on their existing disease conditions, as well as increase the risk for poor long-term neurological and developmental adverse effects. Moreover, our ability to assess and appropriately treat pain in newborn infants and young children is limited. Some studies have concluded that some of the drugs used to control pain, such as continuous intravenous infusion of morphine for pain control in newborn infants, can have significant long-term neurological morbidity. Similarly, the potential effects of maternal pain on the developing fetus have not been studied. For all these and more reasons, attempts to reduce or eliminate pain associated with patient care practices for vulnerable subjects, have potential to positively improve short and long-term outcomes.

Availability of simple lab-on-a-chip methods can enormously aid research in the above noted populations. For instance, over 80% of medications used in the NICU are not labelled for newborn use, essentially because pharmacological studies in tiny infants are inherently difficult since there is a need for obtaining blood.

Over 80% of drugs used for treating newborn infants in the intensive care units are off-label; they have not been well tested in this population. Similarly,

research is limited on drugs given to pregnant and lactating women for safety and efficacy. A similar situation exists when one considers the use of drugs, medications, and vaccines during pregnancy and lactation.

One of the hurdles for developing a strong evidence base in this field is the lack of simple, non- or-minimally invasive methodologies for measuring and monitoring biochemical variables during pharmacological research. The requirement for obtaining blood samples and other biological specimens repeatedly leads to difficulty in obtaining IRB approvals, and adds to the complexity of conducting research in pregnant and lactating women, and in sick infants and children.

Thus, development of non- or minimally-invasive methods to measure and monitor commonly evaluated biochemical substances, and using integrated platforms for measuring multiple analytes using single samples may help solve clinical and research needs in the perinatal, neonatal and pediatric populations. This FOA therefore is being proposed to stimulate bioengineering scientists to collaborate with the biomedical research community and to develop non- or minimally invasive methods and platforms to facilitate both research and clinical care in this critical area of perinatal and neonatal medicine.

Scope

This FOA is to stimulate the bioengineering research community to develop non- or minimally-invasive methods for biochemical and physiological variables to help in clinical monitoring and research. Applications should describe projects to develop non- or minimally-invasive methods for testing analytes and physiological variables, including but not limited to: serum electrolytes; liver function tests (e.g., liver enzymes, bilirubin); renal functions (e.g., blood-urea nitrogen, creatinine); biomarkers of infection and inflammation; metabolic by-products of drugs; concentrations of drugs used in clinical care or research and physiological variables affected by cardiopulmonary and metabolic systems.

Sources for developing the noted monitoring could include, but are not limited to: trans-epidermal; transcutaneous using nano-sized electrodes; saliva and other body fluids.

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